

Remarks

Claims 1, 3-12, 15-26, 30-42, 45, 46, 50-52, and 55-66 were pending. Claim 1 has been amended above.

Claim 1 has been amended to remove a numerical limitation previously presented. Given the new Examiner in this case, and in turn, new references and corresponding bases for rejection, Applicant is clearly permitted to remove a limitation that had been added in an attempt to facilitate prosecution that was focused on different references and bases.

With respect to the present Action, the Section 102(e) rejection based on Gizurarson (the '503 patent) is respectfully traversed. The rejection is confusing since it seems to be premised on the existence of a common inventor with the instant application, where in fact there is no actual, or even apparent, relationship between the two cases or their inventors.

Nor does the '503 patent teach or suggest the present invention. As explained in Applicant's own specification and at length in previous correspondence with the Office, the present claims are directed to the *buccal* delivery of an inactivated bioactive peptide by the use of particular enhancers, in the form of quaternary ammonium salts such as benzalkonium chloride.

At the outset, it is clear that the '503 patent fails entirely to teach a peptide of the type, or for the purpose, presently claimed, and instead is concerned only with the delivery of antigenic compounds. Moreover, reference to benzalkonium chloride appears only twice in the '503 patent, first as an example of suitable preservatives (col. 9, lines 24-27), and separately, within a list of "pharmaceutically acceptable excipients" at column 19, lines 19. These isolated and unrelated occurrences most certainly do not rise to the level necessary to anticipate the present invention.

The Section 103 rejection is respectfully traversed. Taken both individually, and certainly in any permissible combination, the cited references fail entirely to teach or suggest even the elements of the invention as presently claimed, let alone to the extent that would be required to obviate this invention. Instead, the rejection is based upon three references that each appear to be cited for the mere occurrence of various keywords somewhere within their texts.

Hale (US 5,607,691) itself relates to a system in which pharmaceutical agents are said to be bonded to chemical modifiers via physiologically cleavable bonds. There seems to be but a single reference to benzalkonium chloride (col. 47, line 64), under the heading of "transdermal delivery", and in turn, within a list of "other items" that may be contained in a transdermal delivery device. Even then, the compound is included as but an example of an example (i.e., an example compound of an example ingredient (preservative or bacteriostatic agent)). Clearly nothing in this reference teaches or suggests the use of quaternary ammonium salts, such as benzalkonium chloride, for use as enhancers in the manner presently claimed.

Gizurarson (6,514,503) is discussed above, and certainly does nothing to remedy these defects of Hale itself.

Nor does Blumberg et al. (US 6,030,613) remedy the various defects set forth above. Blumberg et al. also relate to materials and methods for initiating an immune response, and in particular, by conjugating therapeutics to a particular binding partner (FcRn receptor). The various materials of Blumberg et al., and their use, are again more dissimilar than they are similar to those of the present invention. As above, benzalkonium chloride is discussed only once and in passing (col. 14, lines 33-35), and this time within a list of "suitable preservatives", in the course of a discussion regarding buffering agents.

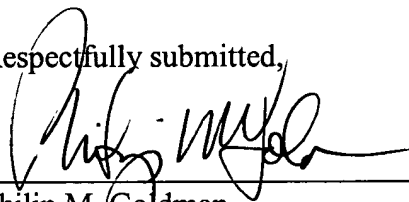
Accordingly, entry of the present Amendment and reconsideration of the pending rejection is respectfully requested. The Examiner is encouraged to telephone the undersigned in the event any remaining issues arise.

The Commissioner is hereby authorized to charge any additional filing fees required to Deposit Account No. 061910.

Dated: _____

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Respectfully submitted,



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